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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,870	09/20/2000	Andrew D. Ellington	119927-1030	8382

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 09/10/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy*

Application No.

09/666,870

Applicant(s)

ELLINGTON ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Joseph McKane, Supervisory Patent Examiner, at (703) 308-4537. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-30, drawn to a device for “automatically selecting an aptazyme”, classified variously in class 435, subclass 287.2, FOR 210 (935/85), DIG 45.
 - II. Claims 31-37, drawn to an “automated method” for “selecting aptamer oligonucleotides”, classified variously in class 935, subclass 87; 435, subclass 91.31; class 536, subclass 24.5, 25.31, 25.32, 25.33, 25.34, 25.4; class 435, FOR 202-204 (i.e., 935/77-79); class 435, DIG 2.
 - III. Claims 38-46, drawn to a product described as “a substrate that produces a signal when an aptazyme reaction occurs”, classified variously, for example, in class 435, subclass 7.72, DIG 49.
 - IV. Claims 47-53, drawn to a method for “detecting an aptazyme reaction”, classified variously in class 435, subclass 91.31; class 536, subclass 24.5, 25.31, 25.32, 25.33, 25.34, 25.4; class 435, FOR 202-204 (i.e., 935/77-79); class 435, DIG 2.

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2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using the product, for example, the product could be used for protein and/or nucleic acid synthesis or preparing an array of samples for sequencing and/or NMR and Mass spectral analysis.

4. Groups I and III represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group I programmable robot with reservoirs for reagents and a magnetic bead separator module and a thermal cycler module, whereas Group III is a substrate that produces a signal when an aptazyme reaction occurs. These products are completely different in form and effect and have completely different uses. The invention of Group I requires a programmable robot with reservoirs for reagents and a magnetic bead separator module and a thermal cycler module, which are materials that Group III does not require. As a result, Group I produces different result than Group III i.e., Group I is an apparatus that is used to automatically select for an aptazyme whereas Group III is a product that produces a signal when an aptazyme reaction

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occurs. Therefore, Groups I and III have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Groups I and IV represent separate and distinct inventions because Group I claims an apparatus whereas Group IV claims a method. However, if applicant were to argue that Groups I and IV were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using the product, for example, the product could be used for protein and/or nucleic acid synthesis or preparing an array of samples for sequencing and/or NMR and Mass spectral analysis.

6. Groups II and III represent patentably distinct inventions because Group II represents a method whereas Group III represents a product. However, if applicants were to argue that Groups II and III were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, for example, the process for using the product could be practiced with a substrate that does NOT produce a signal when an aptazyme reaction occurs.

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Therefore, Groups III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. Groups II and IV represent patentably distinct methods. The methods are patentably distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group II requires the use of a “programmable robot having a programmable robotic arm ... [and] a worksurface accessible to the robot, the worksurface having modules including reservoirs for reagents and pipette tips, a magnetic bead separator, an enzyme cooler and a thermal cycler”, which are not required by the method of Group IV. As a result, Group II requires a different reagent and/or materials (robot, magnetic bead separator, enzyme cooler, thermal cycler, etc) that is not required by Group IV. In addition, since Group IV does not utilize the same reagents and/or materials as Group II, Group IV will produce different results than Group II in situations where these materials are required i.e., Group II is a method for selecting aptamer oligonucleotides whereas Group IV is a method for an aptazyme reaction. Therefore, Groups II and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

8. Groups III and IV represent patentably distinct inventions because Group IV represents a method whereas Group III represents a product. However, if applicants were to argue that Groups III and IV were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, for example, the process for using the product could be practiced with a substrate that does NOT produce a signal when an aptazyme reaction occurs. Therefore, Groups III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

10. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

11. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Note: Applicant must select only one species from each subgroup below and applicant must indicate which claims read on each elected species i.e., which claims read on ONLY subgroup 1, which claims read on ONLY subgroup 2, etc. Claim 1 is generic.

Subgroup 1: Species of adaption

A. Device is adapted for selection of DNA (claim 9)

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- B. Device is adapted for selection of RNA (claim 10)
- C. Device is adapted for selection of ribozymes (claim 11)
- D. Device is adapted for selection of phage display proteins (claim 12)
- E. Device is adapted for selection of cell-surface displayed proteins (claim 13)
- F. Device is adapted for selection of biological warfare agents (claim 14)

Subgroup 2: Species of aptazyme

- A. Aptazyme comprises RNA (claim 15)
- B. Aptazyme comprises DNA (claim 16)

Subgroup 3: Species of effector molecule source

- A. Effector is endogenous (claim 19)
- B. Effector is exogenous (claim 20)

Subgroup 4: Species of effector molecule

- A. Effector comprises protein (claim 21)
- B. Effector comprises pharmaceutical agent (claim 22)
- C. Effector comprises protein complex (claim 23)

Subgroup 5: Species of expression

- A. up-regulated (claim 24)
- B. down-regulated (claim 25)

12. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Note: Applicant must select only one species from each subgroup below and applicant must indicate which claims read on each elected species i.e., which claims read ONLY on subgroup 6, which claims read ONLY on subgroup 2, etc. Claim 31 is generic.

Subgroup 6: Species of adaption

- A. Device is adapted for selection of DNA (claim 32)
- B. Device is adapted for selection of RNA (claim 33)
- C. Device is adapted for selection of ribozymes (claim 34)
- D. Device is adapted for selection of phage display proteins (claim 35)
- E. Device is adapted for selection of cell-surface displayed proteins (claim 36)
- F. Device is adapted for selection of biological warfare agents (claim 37)

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13. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

19. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will

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not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
September 8, 2002

BENNETT CELSA
PRIMARY EXAMINER



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